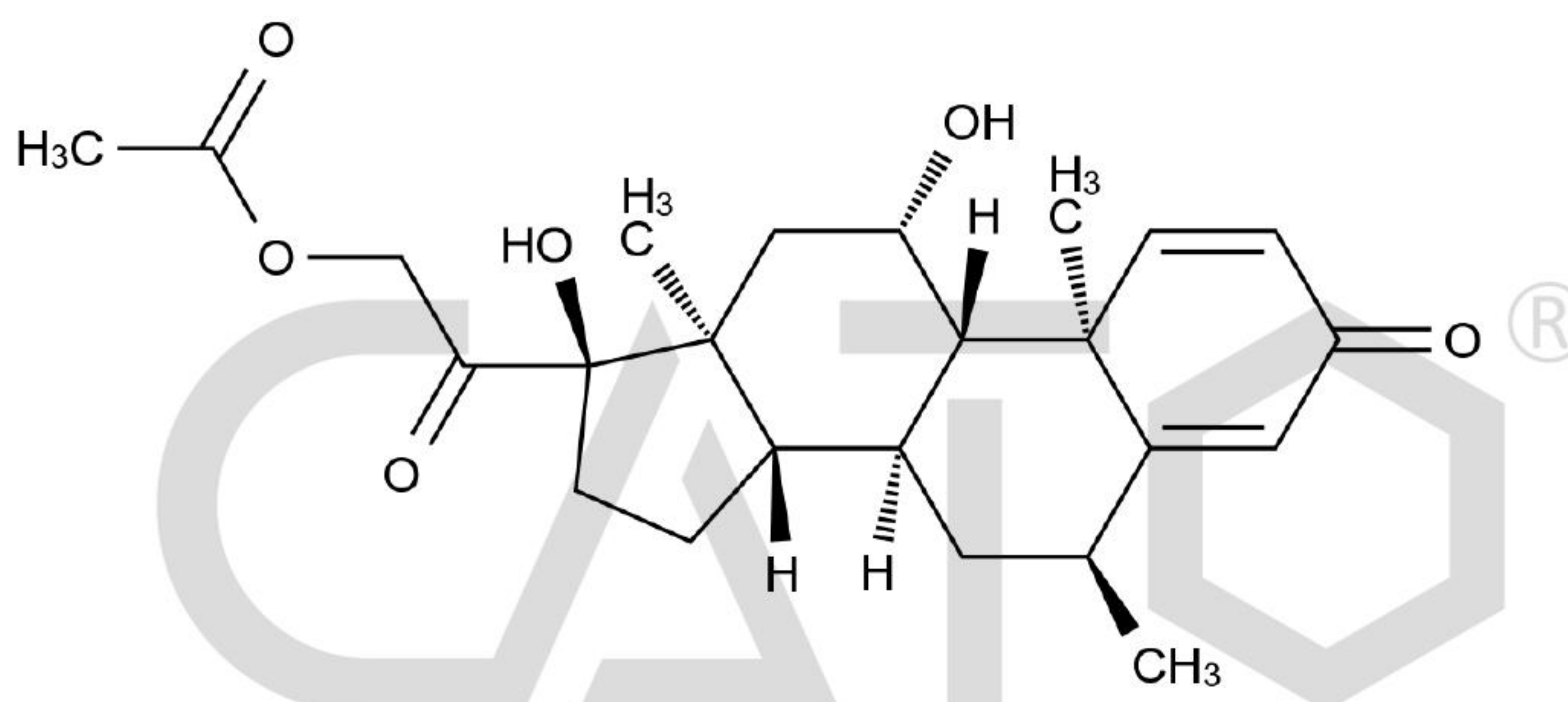


Certificate of Analysis

Reference Material & Standard

Product Name:	Methylprednisolone EP Impurity J	Catalogue Number:	C4X-19192
Synonyms:	Methylprednisolone Acetate/Methylprednisolone Hydrogen Succinate EP Impurity C	Lot Number:	0422-RD-0043
CAS Number:	53-36-1	Expiry Date:	Aug 28, 2027
Molecular Formula:	C ₂₄ H ₃₂ O ₆	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	416.51		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.482%
Loss On Drying	TGA	0.0408%
Assay		99.4%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Aug 29, 2024

Date: Aug 29, 2024

Date: Aug 29, 2024

